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Express Mail No. EV913401130US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of:	Ding *et al.*	Confirmation No.:	3400
Serial No.:	10/679,057	Art Unit:	1762
Filed:	October 3, 2003	Examiner:	Michener, Jennifer Kolb
For:	MEDICAL DEVICES WITH POROUS SURFACE FOR CONTROLLED DRUG RELEASE AND METHOD OF MAKING THE SAME	Attorney Docket No: CAM No.:	10177-239-999 008563-999236

BRIEF ON APPEAL FEE TRANSMITTAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An original and two copies of the applicant's Brief on Appeal in the above-entitled application are submitted herewith. The item(s) checked below apply:

☒ The Brief filing fee is $500.00.

☐ Applicant has qualified for the 50% reduction in fee for an independent inventor, nonprofit organization or small business concern and the Brief filing fee is $250.00.

The brief filing fee is:

☒ Required.

☐ Not required. (Fee paid in prior appeal.)

Please charge the required Brief filing fee to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed.

Respectfully submitted,

Date: January 5, 2007

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Enclosure

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APPEAL BRIEF

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Alexandria, Virginia 22313-1450

Sir:

This is an appeal pursuant to the provisions of 35 U.S.C. § 134 and 37 C.F.R. §§ 41.35 and 41.37 from a final rejection mailed December 13, 2005, of claims 1, 3, 4 6-8, 11-13, and 29 of the above-identified application. The Notice of Appeal was filed on June 5, 2006.

Appellant submits this appeal brief accompanied by (1) a Petition for Extension of Time for five (5) months from August 5, 2006, up to and including January 5, 2007, accompanied by the appropriate fee; and (2) a Brief on Appeal Fee Transmittal Sheet.

Please charge the required fees to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed.

I. REAL PARTY IN INTEREST

The real party in interest is Boston Scientific Scimed, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellant, Appellant's legal representative or assignee, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 3, 4, 6-8, 11-13, and 29 are rejected.
Claims 2, 5, 9, 10, and 14-28 are cancelled.
Claims 1, 3, 4, 6-8, 11-13, and 29 are appealed.

IV. STATUS OF AMENDMENTS

Appellant filed an Amendment under 37 C.F.R. § 1.116 on February 22, 2006, requesting that the Patent Office amend claim 1 and cancel claim 29. The Advisory Action dated March 15, 2006, indicated that the proposed amendments were not entered because they raise new issues that would require further consideration and/or search. A Pre-Appeal Brief Request for Review was filed June 5, 2006, requesting review of the final Office Action dated December 13, 2005. The Patent Office issued a decision on June 29, 2006, maintaining the rejection of claims 1, 3, 4, 6-8, 11-13, and 29. A copy of the claims at issue in this appeal is present in Appendix A.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The presently claimed invention is directed to a method of making a stent having a portion that is insertable or implantable into the body of a patient for delivering a biologically active agent, such as a drug, to the body. These claimed stents have a sidewall comprising a plurality of openings. Examples of these stents are set forth in the specification on page 5, lines 6-16. At least a part of the stents of the claimed invention, such as a surface of the sidewall which may be adapted for exposure to body tissue of the patient, are formed of a porous material having a plurality of voids. (*See, e.g.* specification, page 3, lines 10-31; claims 1 and 29.)

The method of the present invention is directed to using an electric current and electrodes to load a biologically active material, such as a drug, into the voids of the porous material that forms at least a portion of the stent. More specifically, the method comprises forming a solution or suspension of the biologically active agent (*see e.g.,* specification at page 4, lines 11-13). The stent, which has at least a portion formed from a porous material, is placed into this solution or suspension. An electrode is also placed into the solution or suspension (*see e.g.,* specification at page 4, lines 13-14; page 10, lines 11-12; and Figures 1b and 2). An electric current is applied to the stent and the electrode (*see e.g.,* specification at page 4, lines 14-16; and page 10, lines 12-14) and at least some of the biologically active agent in the solution or suspension is allowed to be loaded into the voids of the porous material (*see* specification at page 4, lines 16-19; and page 10, lines 14-26). The biologically active agent is releasable from the voids of the porous material of the stent when the stent is inserted or implanted into the body of a patient (*see, e.g.,* specification at page 1, lines 7-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issue is presented for review in this appeal:

Whether claims 1, 3, 4, 6-8, 11-13, and 29 are unpatentable under 35 U.S.C § 103(a) over U.S. Patent No. 5,843,172 to Yan ("Yan") in view of U.S. Patent No. 5,205,921 to Shirkanzadeh ("Shirkanzadeh").

VII. ARGUMENT

A. Relevant Law on Obviousness

The Patent Office bears the burden of establishing a prima facie case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). A finding of obviousness requires that the prior art both suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Both the suggestion and the reasonable expectation of success must be adequately found in the prior art, not in an applicant's disclosure. *In re Deuel*, 51 F.3d at 1558. Further, where combinations of art are involved, there must be a reason or suggestion in the art for combining the art as proposed. *In re Otiker*, 977 F.2d 1443, 1448 (Fed. Cir. 1992). In order for the cited references to be combined together to render the claimed invention unpatentable, the references must provide some motivation to make the combination. *Northern Telecom, Inc. v. Datapoint, Corp.*, 908

F.2d 931, 934 (Fed. Cir. 1990) (it is insufficient that the prior art separately discloses the components of the claimed invention; there must be some suggestion, teaching or incentive in the prior art to make the combination made by the inventor).

Thus, to establish a prima facie case of obviousness, the Patent Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process; the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success; and the prior art teaches or suggests all the claim limitations. MPEP § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner's conclusory statements cannot form a basis for a prima facie case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

It is well-established that "a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02, *citing W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (emphasis in the original). Moreover, "in determining whether . . . a suggestion can be fairly gleaned form the prior art, the full field of the invention must be considered." *In re Dow Chemical Co.*, 5 U.S.P.Q.2d at 1531 (Fed. Cir. 1988).

Moreover, the Federal Circuit has made very clear that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

B. The References

1. Yan

Yan discloses a metallic stent, which is used in a body lumen, *i.e.* soft tissue, having pores in the metal for containing a medication. (*See* abstract). More specifically, Yan teaches loading a medication into the pores of a metallic vascular stent. (*See* abstract). After the stent is implanted or inserted, the medication is released from the stent into the vascular tissue or blood vessel. (*See* abstract). Yan does not teach a method involving an electrode for depositing its releasable mediation into the pores of its stent.

2. Shirkanzadeh

Shirkanzadeh discloses a "process for the deposition of ceramic coatings, particularly oxide and phosphate coating on porous and nonporous conducting substrates" such as stainless steel, titanium, or alloy implantable prostheses. Column 1, lines 57-59; and column 2, lines 17-19. Such prostheses include ones for use with hard tissues, such as an orthopedic prostheses, artificial teeth (column 1, lines 14-16), and knee or hip replacement prostheses (column 2, line 20). Shirkanzadeh states that "[i]t is known that coating prosthetic implant devices such as porous coated orthopaedic prostheses, artificial teeth and the like with an oxide or phosphate coating improves the effectiveness and biocompatibility of the device by stimulating bone in-growth or by even bonding chemically to the bone structure." (Column 1, lines 14-19).

Shirkanzadeh states that the coating containing the deposited ceramic compound remains on the implant as an "adherent film" (column 2, lines 44-45) and the coating is "firmly adhered to the substrate" (column 3, lines 35-39). Shirkanzadeh teaches that coating containing the deposited ceramic compound is adherent to the prosthesis so that the prosthesis would eventually bond chemically to the bone structure. (Column 1, lines 14-19).

In addition, Shirkanzadeh discloses that "the calcium phosphate coating is composed of an interlocking network of non-oriented crystals with micro pores and that the coating is firmly adhered to the substrate" and that the "coated substrate therefore provides a large surface area of the calcium phosphate crystals in contact with body fluids when used as an implant." (Column 3, lines 35-42).

Shirkanzadeh does not disclose or suggest the use of a stent having a sidewall with a plurality of openings therein. Shirkanzadeh also does not disclose or suggest a method that includes the use of electrodes to draw a biologically active material into porous material of a medical device prior to insertion or implantation into the body of a patient. Shirkanzadeh does not provide any indication that its phosphate or oxide compounds can be drawn into the pores of the substrate. For example, Shirkanzadeh does not discuss pore size. In fact, Shirkanzadeh is completely silent as to whether its phosphate or oxide compounds are actually deposited into the voids of the porous material.

C. Claims 1, 3, 4, 6-8, 11-13, and 29 are Patentable Over Yan and Shirkanzadeh

Independent claim 1 recites a method of making a stent wherein the stent comprises a surface formed of a porous material having a plurality of voids therein to release at least one biologically active agent therefrom, the method comprises forming a solution or suspension of the biologically active agent; placing the stent into the solution or suspension; placing an electrode in the solution or suspension; applying an electric current to the stent and the electrode; and allowing at least some of the biologically active agent to be loaded into the voids, wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body. Claims 3, 4, 6-8, 11-13 depend from claim 1 and, thus, also include such recitations. Independent claim 29 similarly recites a method of making a stent wherein the sidewall has a surface adapted for exposure to body tissue of the patient.

In short, in the present invention, the voids of a porous material are loaded with a biologically active agent using an electrode, and the biologically active agent is releasable upon insertion of the stent into the body. Yan and Shirkanzadeh do not disclose or suggest the presently claimed invention for the following reasons.

1. **The References Do Not Disclose or Suggest All Claim Limitations**

As acknowledged by the Examiner, Yan "fails to specifically teach . . . an electrodeposition method for loading the stent with the bioactive agent." (December 13, 2005 Office Action, at page 2). In particular, Yan does not disclose or suggest a method comprising loading a porous material with a biologically active agent by: a) forming a solution or suspension of the biologically active agent; b) placing the stent into the solution or suspension; c) placing an electrode in the solution or suspension; d) applying an electric current to the stent and the electrode; and e) allowing at least some of the biologically active agent to be loaded into the voids as recited in claims 1 and 29.

Shirkanzadeh does not remedy the deficiencies of Yan. Shirkanzadeh also does not disclose a method of making a stent comprising loading a porous material with a biologically active agent by, *inter alia*, using an electrode and allowing at least some of the biologically active agent to be loaded into the voids. Shirkanzadeh does not even disclose or suggest a method of making a stent or the use of a stent or any medical device having a sidewall with a plurality of openings therein. Shirkanzadeh also does not disclose or suggest a biologically active agent is releasable from the stent upon insertion into the body, as required by the present claims

Thus, Yan in view of Shirkanzadeh do not disclose or suggest all limitations of the presently claimed method of making a stent by, *inter alia*, loading a biologically active material into the voids of a porous material of a stent.

2. There is No Motivation to Combine the References

Appellant further submits that even if the combination of Yan and Shirkanzadeh discloses the presently claimed invention, which it does not, these two references do not provide motivation to combine their respective teachings. Prior to combining references, the law requires that there must be some suggestion or motivation in the references themselves to modify or combine the teachings of the references. That knowledge cannot come from the applicant's invention or application. *In re Oetiker*, 977 F.2d 1443, 1448 (Fed. Cir. 1992).

a. Shirkanzadeh Teaches Away from the Present Invention

Shirkanzadeh does not teach or suggest and, in fact, teaches away from a method of loading a biologically active agent such as a drug into the voids of the porous material of a sidewall of a stent. Instead, Shirkanzadeh teaches a process for depositing an adherent ceramic compound onto a prosthesis. Shirkanzadeh is completely silent as to whether its phosphate or oxide compound is actually deposited into the voids of the porous material, as required by the present invention. Shirkanzadeh merely teaches that calcium phosphate is "precipitated as a dense, adherent film onto the cathode" rather than deposited into the voids of the device material as in the present invention (column 2, line 44).

Shirkanzadeh does not provide any indication that its porous substrate can be loaded with a biologically active agent. For example, Shirkanzadeh does not discuss pore size and only mentions depositing the coating onto the substrate. In fact, Shirkanzadeh teaches away from loading any substance into the pores prior to implantation by discussing the desired effect of bone ingrowth into the pores, which would occur after implantation. Shirkanzadeh simply does not disclose or suggest and, in fact, teaches away from the step of loading the pores of its substrate with a biologically active agent.

Moreover, it is noted that, in the Final Office Action dated December 13, 2005, the Examiner stated that "Shirkanzadeh teaches electrodepositing a biologically active (bioactive) agent onto porous, metal medical device implant substrates (abstract). Shirkanzadeh forms a solution of the bioactive agent, places the device into the solution with an electrode and applies current to deposit the bioactive agent onto the substrate." Office Action, page 2 (emphasis added). The portions of Shirkanzadeh cited by the Examiner in support of the claim rejection also state that Shirkanzadeh's bioactive agent is deposited onto the substrate. Office Action, page 2.

Shirkanzadeh also does not disclose or suggest, and in fact teaches away from, loading a porous material with a biologically active agent, wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body, as presently claimed.

Contrary to the Examiner's statement that "some portion of the coating of Shirkanzadeh will be released in the body" (page 4 of the Office Action), Shirkanzadeh does not disclose or suggest that its deposited material is releasable upon insertion into the body of a patient. Instead, Shirkanzadeh discloses that the ceramic compounds in the coatings enhance the biocompatibility of the implant by promoting bone ingrowth (column 1, lines 15-19), and that the ceramic compound coating remains on the implant as an "adherent film" and that "[a]dherent coatings" are formed (column 2, lines 38-46) and that the coating is "firmly adhered to the substrate" (column 3, lines 35-39). Shirkanzadeh teaches that the adherent film improves the effectiveness and biocompatibility of the prosthesis by stimulating bone in-growth or by even bonding chemically to the bone structure even after implantation or insertion of the prosthesis into the body of a patient. (*See, e.g.*, column 1, lines 15-19; column 3, lines 35-39). Shirkanzadeh further states that "the ultimate objective of the present technique is to provide a phosphate coating which will enhance calcified tissue formation within the pores of the metal substrate" and that "the eventual bonding of the tissues to the prosthesis occurs through the mechanical interlock between porous metal and bone." Column 2, line 66, to column 3, line 4.

If the coating in Shirkanzadeh were releasable, it would undermine the purpose of stimulating bone growth and the mechanical interlock between the porous metal and bone, and chemically bonding to the bone structure after implantation. Thus, Shirkanzadeh clearly teaches away from loading the voids of a porous material of a stent (or any medical device) with a biologically active agent that is releasable from the stent or device upon insertion into the body of a patient.

Accordingly, one skilled in the art would not find motivation in the disclosures of Yan and Shirkanzadeh to combine the teachings of these references to obtain the present invention, where Yan does not disclose or suggest the specific method of loading a stent with a biologically active agent as presently claimed and Shirkanzadeh does not disclose or suggest the use of a stent and in fact teaches away from loading the voids of a porous material of a stent (or any medical device) with a biologically active agent that is releasable from the stent or device upon insertion into the body of a patient.

The Examiner stated on page 5 of the Office Action and in the Advisory Action dated March 15, 2006, that the coatings of Yan are adherent prior to implantation and suggests that this provides the motivation to combine. The Examiner does not point to those parts of Yan that show that the coating of Yan is allegedly described as "adherent". Nevertheless, for argument's sake, assuming Yan teaches an adherent coating before implantation, since Yan teaches that the bioactive agent in its stent is releasable when or after the stent is implanted and Shirkanzadeh teaches that the bioactive agent of its device is not releasable after implantation, Examiner's assertion that Yan's coating is adherent before implantation is irrelevant and also fails to establish that there is any motivation to combine the teachings of Yan and Shirkanzadeh.

On pages 4-5 of the Office Action, the Examiner also stated that there is motivation to combine Yan and Skirkanzadeh since "all coatings are releasable (able to be released), including 'at least some' of otherwise adherent coatings." The Examiner reiterates this point in the Advisory Action. However, the Examiner does not point to any support that all coatings, including those of Skirkanzadeh, would be releasable. To the extent that this assertion is based on facts within the Examiner's personal knowledge, the Examiner has not provided an affidavit pursuant to the provisions of 37 C.F.R. § 1.104(d)(2) and simply restated in the Advisory Action that it is well-known that under certain circumstances, all coatings can be released to some degree. Appellant submits that the showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence. *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313, 63 USPQ2d 1374 (Fed. Cir. 2002), *citing, In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

b. **The References are Directed to Different Problems to be Solved**

Appellant further submits that there is no motivation to combine the teachings of Yan and Shirkanzadeh because the nature of the problem to be solved is different in each of these references. Specifically, Yan and Shirkanzadeh each teaches medical devices designed for very different uses. As discussed above, Yan teaches an intra-vascular prosthesis, such as a stent (column 1, lines 7-10), which is used for a body lumen or soft tissue. The purpose of the stent is to keep the vessel open and prevent restenosis or closing of the vessel. In contrast, Shirkanzadeh discloses prosthetic devices for use with hard tissue, such as an orthopedic prosthesis, artificial teeth, and knee or hip replacement prostheses (column 1, lines 14-16; and column 2, line 20). For example, Shirkanzadeh is directed to prosthetic implants such as bone implants, which are designed to stimulate bone growth. Thus, the two devices have completely opposite purposes and one skilled in the art would not expect that the device or method of Shirkanzadeh would apply to that of Yan and vice versa. Accordingly, one skilled in the art would not be motivated to combine the teachings of Shirkanzadeh and Yan because each teaches a device that is used in significantly different tissue types, *i.e.,* and soft tissue versus hard tissue.

There is also no motivation to combine the teachings of Yan and Shirkanzadeh since each of these references discloses medical devices having a medication or bioactive agent that serves a different purpose or achieves a different result when such medical devices are inserted or implanted. Yan teaches that the medication or bioactive agent of its vascular stent is releasable upon implantation. In contrast, Shirkanzadeh teaches a bioactive coating adherently disposed on the device and a method for forming an orthopedic device in which a bioactive agent is not releasable from the device after implantation. Since these two references teach that the bioactive agent in their respective medical devices have different purposes and achieve different results when each device is implanted or inserted, *i.e.* in one the bioactive agent is released from the device after implantation, while in the other the bioactive agent adheres to the device after implantation, the skilled artisan would not be motivated to combine the teachings of Yan and Shirkanzadeh. Such conflicting teachings cannot reasonably be viewed as suggesting their combination. *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 58 USPQ2d 1286 (Fed. Cir. 2001).

It is respectfully submitted that one skilled in the art would not find motivation in the disclosures of Yan and Shirkanzadeh to combine the teachings of these references to obtain the presently claimed invention absent hindsight analysis. The Federal Circuit has made very clear that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

3. There is No Reasonable Expectation of Success

Furthermore, there is no reasonable expectation of success that applying Shirkanzadeh's method of making an adherent coating to Yan's stent would result in a releasable coating of the presently claimed invention. Thus, since Yan and Shirkanzadeh are directed to completely opposite purposes as discussed above, one skilled in the art would not expect that the device or method of Shirkanzadeh would apply to that of Yan and vice versa. In fact, by teaching that its method leads to an orthopedic device in which the active agent is not released from the device after implantation, Shirkanzadeh teaches away from the claimed invention in which the biologically active agent is released from the voids after implantation or insertion of the stent.

A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Here, the Examiner failed to consider Shirkanzadeh in its entirety and thereby ignored those portions of the reference that argued against obviousness and erroneously combined Yan and Shirkanzadeh.

Thus, a *prima facie* case of obviousness has not been made with regard to independent claims 1, its dependent claims, and independent claim 29 because the Examiner failed to show that the cited references, Yan and Shirkanzadeh, either alone or together, teach or suggest the present invention. Furthermore, the Examiner failed to show any suggestion or motivation to combine the cited references, or a reasonable expectation of success.

Accordingly, it is believed that independent claims 1 and 29 and claims 1, 3, 4, 6-8, 11-13 and 29 depending from claim 1, are patentable over Yan and Shirkanzadeh, whether taken alone or in combination.

VIII. CONCLUSION

For all of the reasons set forth above, Appellant respectfully requests that the rejection of claims 1, 3, 4, 6-8, 11-13, and 29 be reversed.

Respectfully submitted,

Date: January 5, 2007

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Appendix A: CLAIMS ON APPEAL

Appendix B: EVIDENCE

Appendix C: RELATED PROCEEDINGS

APPENDIX A

CLAIMS ON APPEAL

1. (Previously presented) A method of making a stent having at least a portion for insertion or implantation into the body of a patient, wherein the stent comprises a sidewall having a plurality of openings therein and wherein at least a part of the sidewall comprises a surface formed from a porous material having a plurality of voids therein to release at least one biologically active agent therefrom, the method comprising loading the porous material with the biologically active agent by:

a) forming a solution or suspension of the biologically active agent;
b) placing the stent into the solution or suspension;
c) placing an electrode in the solution or suspension;
d) applying an electric current to the stent and the electrode; and
e) allowing at least some of the biologically active agent to be loaded into the voids,

wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body.

3. (Original) The method of claim 1 wherein the electrode functions as a cathode and the biologically active agent has a negative charge.

4. (Original) The method of claim 1 wherein the electrode functions as an anode and the biologically active agent has a positive charge.

6. (Previously presented) The method of claim 1 wherein the stent comprises a metallic material.

7. (Original) The method of claim 6 wherein the stent is a self-expanding stent.

8. (Original) The method of claim 6 wherein the stent is a balloon-expandable stent.

11. (Original) The method of claim 1 wherein the biologically active agent is heparin.

12. (Previously presented) The method of claim 1 wherein the biologically active agent is loaded immediately before implantation of the stent.

13. (Previously presented) The method of claim 1 wherein at least some of the voids contain a particulate material prior to placing the stent into the solution or suspension.

29. (Previously presented) A method of making a stent having at least a portion for insertion or implantation into the body of a patient, wherein the stent comprises a sidewall

having a plurality of openings therein, and wherein the sidewall has a surface adapted for exposure to body tissue of the patient, and wherein at least a part of the surface of the sidewall is formed from a porous material having a plurality of voids therein to release at least one biologically active agent therefrom, the method comprising loading the porous material with the biologically active agent by:

a) forming a solution or suspension of the biologically active agent;
b) placing the stent into the solution or suspension;
c) placing an electrode in the solution or suspension;
d) applying an electric current to the stent and the electrode; and
e) allowing at least some of the biologically active agent to be loaded into the voids,

wherein at least a portion of the biologically active agent is releasable from the stent upon insertion into the body.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.